REMARKS

I. Background

The present Amendment is in response to the Examiner's Final Office Action mailed April 17, 2007. Claims 1, 2, 3, 5, 7-10, and 12-22 were rejected under 35 U.S.C. 103 (a) as being unpatentable over *Green et al.*, U.S. Patent No. 5,674,231, in view of *Martinez et al.*, U.S. Patent No. 5,593,412. Claims 1, 2, 3, 5, 7-10, and 12-22 are now pending. Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.[1]

II. Rejections on the Merits

A. Rejections Under 35 U.S.C. § 103

According to the applicable law, a claimed invention is unpatentable for obviousness if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art" 35 U.S.C. § 103(a) (2005); *Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966); *MPEP § 2142*. Obviousness is a legal question based on underlying factual determinations including: (1) the scope and content of the prior art, including what that prior art teaches explicitly and inherently; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *Graham*, 383 U.S. at 17-18; *In re Dembiczak*, 175 F.3d 994, 998 (Fed. Cir. 1999). It is the initial burden of the PTO to demonstrate a *prima facie* case of obviousness, which requires the PTO to show that the relied upon references *teach or suggest* all of the limitations of the claims. *MPEP § 2142* (emphasis added). To be combined, the references should be analogous. In particular, "[a] prior art reference is analogous if the reference is in the field of applicant's endeavor or, if not, the

[1] Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicants request that the Examiner carefully review any references discussed below to ensure that Applicants' understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

reference is reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1446 (Fed. Cir. 1992)(*see MPEP § 2145*).

1. Rejection of Claims 1, 2, 3, 5, 7-10 and 12-22

Claims 1, 2, 3, 5, 7-10 and 12-22 were rejected under 35 U.S.C. § 103 as being unpatentable over *Green et al.* (U.S. Patent No. 5,674,231) in view of *Martinez et al.* (U.S. Patent No. 5,593,412). Applicants respectfully traverse.

In *Green et al.*, "in use, the elongated body of surgical apparatus 10 is introduced into the interior lumen 102 of blood vessel 104 though a conventional cannula 100" (Col. 7, ll.18-20). Once in place, the "locator 60 is moved distally through the translation of control knob 75" (Col. 7, ll. 23-24). The "locator 60 is [then] advanced from its proximal-most position . . . to its distal-most position . . . [with] the arcuate expansion portions 62b and 64b . . . in a collapsed (stressed) condition" (Col. 7, ll. 25-31). "[A]fter locator 60 is moved into its distal position, *cannula 100 is withdrawn* in a proximal direction with respect to elongated body 20 to a retracted position . . . [and] the arcuate expansion portions 62b and 64b of locator arms 62 and 64 move into their deployed (unstressed) positions" against the blood vessel (Col. 7, ll. 38-43)(emphasis added).

In contrast to *Green et al.*, independent claim 1 recites in part "expanding said one or more positioning elements from a non-stressed state to a stressed state; withdrawing said locator member until said positioning elements contact tissue; advancing the carrier assembly towards the distal end of the elongate member". In *Green et al.*, "locator 60 [moves] from a collapsed (stressed) position disposed within the axial bore 34a of support fixture 34 to a deployed (unstressed) position extending from the distal end of support fixture 34" (Col. 6, ll. 57-60). Thus, the locator of *Green et al.* is deployed into a unstressed position, whereas the invention of independent claim 1 includes "expanding said one or more positioning elements from a non-stressed state to a stressed state." Therefore, the invention disclosed in *Green et al.* does not contain all of the elements of the deployment of the locator of the present invention of independent claim 1.

Martinez et al. was cited as teaching "a skin, or sleeve, 18 overlying at least a portion of the outer surface between the carrier assembly and a distal end of the elongate member" (Office Action page 3). Even if, arguendo, Martinez et al. discloses such a skin, or sleeve, it fails to

disclose, at least, "expanding said one or more positioning elements from a non-stressed state to a stressed state." as recited in independent claim 1.

Turning to independent claims 17 and 20, Applicants respectfully disagree with the Examiner regarding the combination of *Green et al.* and *Martinez et al.* As mentioned before, *Green et al.* and *Martinez et al.* are directed to conflicting functional operations that result in it being not obvious to combine their teachings. *Green et al.* is a clip applier device and *Martinez et al.* is a stent delivery device. *Green et al.* is directed to "[a]n apparatus and method . . . for *applying a surgical clip to an exterior wall* of a blood vessel to at least partially *close a hole* formed therein" (*Abstract*)(*emphasis added*), while *Martinez et al.* is directed to a "stent delivery method and apparatus" that expands "the balloon and stent *to expand the stent to a desired diameter*" at the stenotic lesion to increase blood flow through the location of the lesion (*Abstract)*. Closing a hole in a blood vessel by applying a clip to an exterior wall of the blood vessel is opposite to opening a vessel by implanting a stent within a lesion within the vessel. Notwithstanding, *arguendo*, that *Green et al.* and *Martinez et al.* disclose delivery or deployment methods, these methods and devices are directed to conflicting devices and conflicting underlying delivery principals. For instance, the underlying purposes of the *Martinez et al.* devices teach away from combining its teaching with *Green et al.* Prior stent on a balloon assemblies "cause[d] trauma to the vessel into which . . . [the assembly was] inserted as it track[ed] through the vessel" (Col. 4, ll. 24-28). To solve this problem, and as taught by *Martinez et al.*, a sheath was placed around the stent. This would reduce trauma to the vessel as it is moved from outside the body to the lesion through the tortuous anatomy of the patient.

Unlike the device of *Martinez et al.*, the device of *Green et al.* passes from outside the body to just inside the blood vessel, as illustrated in Figure 11 of *Green et al.* The vascular hole closure device doesn't need to be navigated through the tortuous anatomy to a stenotic lesion that can be distant from the access hole in the vessel. Inclusion of the sheath of *Martinez et al.* in the device of *Green et al.* would not be necessary because the device of *Green et al.* is deployed into "the interior lumen 102 of blood vessel 104 *through a conventional cannula 100*, which had previously been extended through hole 106 formed in the wall of blood vessel 104 during the catherization procedure" (Col. 7, ll. 19-23)(emphasis added). The cannula provides protection to the surrounding tissue until the clip is to be deployed. As such, it would not be necessary to include the protective sheath of *Martinez et al.* with the device of *Green et al.* since the cannula

provides the desired protection. The only teaching for such a combination is the teaching of Applicants disclosure. Therefore, since the clip of *Green et al.* is advanced "through a conventional cannula", for the reasons above, one of ordinary skill in the art of vessel closure would not be directed to add an additional sheath to the system of *Green et al.*

Furthermore, the use of a "conventional cannula" implies that the cannula of *Green et al.* is not custom made for the device of *Green et al.*, unlike the present invention. The Office Action suggests that the "conventional cannula" can be modified with the sheath of *Martinez et al.* However, there is no reason to make such a change because the cannula performs the desired function of protecting the tissue during insertion of *Green's* delivery device. Thus, Applicants respectfully submit that the Examiner is using the present application in hindsight, impermissibly, to combine the sheath of *Martinez et al.* with the device of *Green et al.*

In addition to the above, the combination of *Green et al.* and *Martinez et al.* do not teach every element of independent claims 17 and 20. In particular, *Martinez et al.* is being cited as disclosing the "a skin, or sleeve, 18 overlying at least a portion of the outer surface between the carrier assembly and a distal end of the elongate member and the carrier assembly causing the skin to separate from the outer surface of the elongate member as the carrier assembly is advanced towards the distal end" (Office Action page 3). Even if, *arguendo*, the "skin, or sleeve" were combined with the cannula of *Green et al.*, the combination would not teach of suggest "advancing the carrier assembly towards a distal end of the elongate member, the advancement of the carrier assembly causing the sleeve member to be disrupted to permit such advancement" of independent claim 17 or "advancing the carrier assembly towards a distal end of the elongate member, the advancement of the carrier assembly causing the sleeve member to be expanded to permit such advancement" of independent claim 20. *Martinez et al.* discloses moving an assembly proximally before deployment of the stent. In particular, *Martinez et al.* teaches pulling the sheath rearwardly or the sheath being "withdrawn from the stent on a balloon assembly" (Col. 5, ll. 3-4). Even if, arguendo, the sleeve of *Martinez et al.* were substituted for the cannula of *Green et al.*, according to the disclosure of *Martinez et al.* the sleeve would expand, for instance, upon movement of the sleeve proximally relative to the clip and locator rather than "advancing the carrier assembly *towards a distal end of the elongate member, the advancement of the carrier assembly causing the sleeve member to be disrupted to permit such advancement*" of independent claim 17 or "advancing the carrier assembly *towards a distal end*

of the elongate member, the advancement of the carrier assembly causing the sleeve member to be expanded to permit such advancement" of independent claim 20 (emphasis added). Rather than teaching disruption or expansion of the sleeve member occurring upon distal movement of the carrier assembly, as recited in independent claims 17 and 20, respectively, *Martinez et al.* teaches proximal movement of the skin or sleeve.

For the reasons stated above, Applicants respectfully submit that the scope and content of *Green et al.* and *Martinez et al.*, nor the level of ordinary skill in the prior art, teaches or suggests combining the device of *Martinez et al.* with the device of *Green et al.* As such, Applicants respectfully request withdrawal of the rejection of claims 1, 2, 3, 5, 7-10 and 12-22 under 35 U.S.C. § 103.

2. Rejection of Claim 6 under 35 U.S.C. § 103

Claim 6 was rejected under 35 U.S.C. § 103 as being unpatentable over *Green et al.* in view of *Martinez et al.* and further in view of *Kanner et al.* (U.S. Patent No. 5,868,755). Since claim 6 depends from independent claim 1, and since *Kanner et al.* does not teach or suggest the invention claimed in independent claim 1 or aid with the combination of *Green et al.* and *Martinez et al.*, Applicants respectfully submit that for the same reasons as those stated above with respect to the combination of *Green et al.* and *Martinez et al.*, the rejection of dependent claim 6 should be withdrawn.

In view of the foregoing, Applicants respectfully submit that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicants acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicants reserve the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicants specifically request that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

CONCLUSION

In view of the foregoing, Applicants believe the claims provided in the claim listing are in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 17th day of August, 2007.

Respectfully submitted,

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